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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,452	09/30/2003	William G. Kerr	1372.79.PRC	2451

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EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/605,452	KERR ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,32,35,39,40,43-47,50 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,32,35,39,40,43-47,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: Sej.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 14, 2006 has been entered.

Claims 1-28, 30-31, 33-34, 36-38, 41-42 are cancelled. Claims 29 and 43 are amended.

Claims 29, 32, 35, 39, 40, 43-47, 50, 51 are under consideration.

New/Maintained Rejections

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with

the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/319,583, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Provisional application 60/319,583 does not provide adequate support or enablement for a method of inducing proliferation in human or mouse ES or hematopoietic cells, wherein proliferation is induced following administration of anti-s-SHIP or SIP-110 shRNA. The specification of the provisional application does not adequately disclose the steps one would take to arrive at the claimed invention. See the rejections under 35 U.S.C. 112, first paragraph, above for an in depth discussion regarding lack of enablement.

As such, the priority for the instant application is September 30, 2003.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29, 32, 40, 43, 44, 47, 50, 51 are newly provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-6 of copending Application No. 10/709,801 ('801) in view of Rohrschneider et al. 2000, Genes and Development, 14: 505-520.

The scope of '801 is broader than that of the instant invention and encompasses the envisioned embodiments of the instant invention. The '801 specification teaches that ES cells were treated with SHIP-specific shRNA vectors ('801 specification, Example 4) and the specification teaches that interference with SHIP function can be used to expand the number of hematopoietic cells ('801 specification, parag. 52 and 53).

It is noted that making shRNA against s-SHIP/SIP-110 (human homolog of mouse s-SHIP) would necessarily target full length SHIP/SIP. For example, Rohrschneider et al. teach that SIP-110 is similar in sequence to full length SIP, but does not have the N-terminal of full length SIP (Rohrschneider et al., Figure 2).

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29, 32, 35, 39, 40, 43-47, 50, 51 remain rejected in modified form under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record August 9, 2005 and April 12, 2006.

Upon further consideration, new issues of rejection have been considered and are discussed below. Following the rejections, the Examiner addresses the Applicant's rebuttals.

The claims are drawn to methods of inducing proliferation of human or mouse ES or hematopoietic cells by introducing an anti-SIP-110 or anti-SHIP shRNA to the cells.

At the time of filing, the art teaches that there is unpredictability in guiding a multipotent cell to a particular fate. Zandstra et al., 2000, Biotechnol. Bioeng., 69: 607-617, teach that a clear understanding of how stem cell genetic programs can be altered by changing the nature or frequency of interactions with their cytokine microenvironment has been technically difficult to address (Zandstra et al., page 608, 1st col., 1st parag.). In the case of the expansion of hematopoietic stem cells, the art teaches that expansion of hematopoietic cells was not routine in the art. Verfaillie, 2002, Nature Immunology, 3: 314-317 teaches that one of the holy grails of stem cell research is *ex vivo* expansion of hematopoietic stem cells (HSCs) (Verfaillie, page 315, 1st col., 1st parag. under "Ex vivo HSC expansion"). Verfaillie teaches that the lack of HSC expansion appears to be

caused by the cell death of one or both HSC progeny cells. Ex vivo culture is associated with increased expression of the Fas ligand CD95 and down-regulation of the anti-apoptosis gene Bcl2 on CD34+ cells; withdrawal from this state activates the caspase pathway in CD34+ cells (Verfaillie, page 315, 2nd col., 5th parag.). Verfaillie also teaches that while microenvironmental signals exist that can activate HSC self-renewal; however, it is not known what signals are involved that support HSC expansion (Verfaillie, page 316, 1st col., 2nd parag.). While the specification teaches that it is envisioned that reducing the expression levels of s-SHIP in mice and SIP-110 in human cells via shRNA would be a way of promoting proliferation (specification, parag. 10), nothing in the art teach that s-SHIP or SIP110 have any role in proliferation in ES or hematopoietic cells. This is an issue as the art teaches that the signals involved in controlling cell fate are not known. As such, without guidance, an artisan cannot arrive at the claimed invention.

At the time of filing, the art teaches that there are differences between mouse cells and human cells that an artisan cannot readily predict that what studies have been carried out in mouse necessarily translate to events that occur in humans. For example, in the case of embryonic stem (ES) cells, Pera et al. 2000, Journal of Cell Science, 113: 5-10, teach that while mouse and human ES cells can originate from a pluripotent cell population, maintain normal karyotype, and are immortal and can be propagated indefinitely in the embryonic state, mouse ES cells can form clonally derived cultures capable of spontaneous differentiation into extraembryonic tissue and somatic cells of all three embryonic germ layers in teratomas or in vitro, whereas human cells

cannot (Pera et al., page 6, under "a generic functional definition of an ES cell"). In the case of hematopoietic cells the art teaches there are human-mouse differences in proteins, such as, human serine proteases. While mice have at least seven mouse mast-cell chymase genes, these are absent in humans (Puente et al., 2003, Nature Reviews: Genetics, 4: 544-558, page 546, 2nd col., 2nd parag.). As these issues apply to the instant invention, because there are differences between mouse and human cells, an artisan cannot reasonably predict that the methods used on human cells will be the same as those used on mouse cells. It is also noted that Puente et al.'s teachings also indicates that an artisan cannot reasonably predict that human ES cells express SIP-110 or that human hematopoietic cells express SIP-110 and full length SIP like the mouse cells. As such, the specification does not provide guidance for an artisan to arrive at proliferating human ES and hematopoietic stem cells, using shRNA against SIP-110.

In addition to this issue, an artisan cannot reasonably predict that the function of s-SHIP in mice is the same as the human homolog, SIP-110. According to the art, not all homologs of proteins have the same function. For example, Rehli et al., 2000, Adv. Exp. Med. Biol., 477: 205-216 teach that carboxypeptidase M (CPM) function in mouse and human macrophages are not conserved (Rehli et al., abstract). As this issue applies to the instant invention, while the specification teaches that the first exons of SIP-110 and s-SHIP show a 82% nucleotide identity (specification, page 42), the specification does not provide guidance that the proteins are functionally conserved such that reduction in s-SHIP in mouse cells and SIP-110 in human cells will

necessarily result in the same phenotype exhibited by the cells (in this case, proliferation). As such, the specification does not provide guidance for an artisan to use the claimed invention.

In addition to these issues, the specification (Figure 8) teaches that the mouse ES cells that were electroporated with shRNA against s-SHIP demonstrated a reduction in s-SHIP levels. This result suggests that the ES cells are hypomorphs for s-SHIP. At the time of filing, the art teaches that phenotypes in hypomorphs are not predictable. For example, Hermann et al., 2003, Nature Genetics, 33: 396-400, teach that when hematopoietic cells transduced with three different retroviral vectors containing shRNAs that target p53 (constructs p53-A, p53-B, and p53-C) were transplanted into irradiated mice, the cells exhibited different phenotypes (Hermann et al., page 398, 1st col., 2nd parag., see also abstract). As this issue applies to the instant invention, an artisan cannot reasonably predict what, if any, phenotypes would be exhibited by the hypomorphic human and mouse ES and hematopoietic cells made by the claimed invention. In addition to this issue, in the event that the cells exhibit an unexpected phenotype, it is unclear what use the claimed cells have. As such, an artisan is not enabled for the full scope of the claimed invention.

The electroporation of anti-s-SHIP shRNA also raises the issue as to whether one dose of anti-s-SHIP shRNA is enough to induce a mouse ES cell to proliferate. The art teaches that one limitation to using shRNA stems from the fact that its effects are transient and restricted by the rate of cell division (and by the fact that mammalian cells do not have the mechanisms to amplify and propagate RNAi (unlike C. elegans and

plants)) (Hannon and Rossi, 2004, Nature 431: 371-378, page 373, 1st col., parag. under "RNAi as a solution for mammalian genetics"). As this applies to the instant invention, it is unclear what method steps would need to be taken such that an artisan knows what dosage of shRNA would need to be administered to the ES cells and hematopoietic cells such that proliferation would occur. As such, the artisan is not enabled for the full scope of the claimed invention.

The claims read on *in vivo* and *in vitro* methods of administering shRNA. At the time of filing, the art teaches that administration of shRNA *in vivo* was not routine in the art. Problems related to therapeutic use of nucleic acids were well known in the art at the time of invention (see for example Opalinska et al., 2002, Nature Reviews Drug Discovery, 1: 503-514). Such problems include the inability to specifically deliver an effective concentration of a nucleic acid to a target cell, such that a target gene is inhibited to a degree necessary to result in a therapeutic effect.

Opalinska et al. state on page 511

> "[I]t is widely appreciated that the ability of nucleic-acid molecules to modify gene expression *in vivo* is quite variable, and therefore wanting in terms of reliability. Several issues have been implicated as a root cause of this problem, including molecule delivery to targeted cells and specific compartments within cells and identification of sequence that is accessible to hybridization in the genomic DNA or RNA"

and in column 2 of the same page,

> "Another problem in this field is the limited ability to deliver nucleic acids into cells and have them reach their target. Without this ability, it is clear that even an appropriately targeted sequence is not likely to be efficient. As a general rule, oligonucleotides are taken up primarily through a combination of adsorptive and fluid-phase endocytosis. After internalization, confocal and electron microscopy studies have indicated that the bulk of the oligonucleotides enter the endosome-lysosome compartment, in which most of the material becomes either trapped or degraded."

Given this unpredictability, the skilled artisan would require specific guidance to practice the claimed methods *in vivo*, with a resultant inhibition of gene expression, as claimed.

The specification provides examples (e.g. see specification, Figure 8), however, cell culture examples are generally not predictive of *in vivo* inhibition and the methods of delivery of the exemplified cell line would not be applicable to delivery of oligonucleotides to any organism. Due to differences in the physiological conditions of a cell *in vitro* versus *in vivo*, the uptake and biological activity observed *in vitro* would not predictably translate to *in vivo* results. Given these teachings, the skilled artisan would not know *a priori* whether introduction of oligonucleotides *in vivo* by the broadly disclosed methodologies of the instant invention, would result in the oligonucleotide reaching the proper cell in a sufficient concentration and remaining for a sufficient time to provide successful inhibition of expression of a target gene. In fact, the state of the art is such that successful delivery of oligonucleotide sequences *in vivo* or *in vitro*, such that the polynucleotide or oligonucleotide provides the requisite biological effect to the target cells/tissues/organs, must be determined empirically. The specification does not provide the guidance required to overcome the art-recognized unpredictability of using nucleic acids in therapeutic applications in any organism. The teachings of the prior art do not provide that guidance, such that the skilled artisan would be able to practice the claimed therapeutic methods. Thus, while the specification is enabling for the examples set forth in the specification, the specification is not enabling for the broad claims of inhibiting the expression of any target gene in any organism as the art of inhibiting gene expression by introducing antisense oligonucleotides into an organism is neither routine nor predictable. The amount of experimentation required is such that one of skill in the art could not practice the invention commensurate in scope with the claims without

undue, trial and error experimentation and therefore, the claims are not enabled for its full breadth of *in vivo* applications.

In addition to these issues, claims 35 and 45 indicate that SIP-110 or s-SHIP comprises the sequences of SEQ ID NOs. 1-3. However, according to a sequence search (see provided copies), SEQ ID NOs 1-3 do not encode any SIP-110 or s-SHIP. Subsequently, it is unclear what SEQ ID NOs 1-3 are and it is unclear how to generate anti-s-SHIP or SIP-110 shRNA against an unknown sequence.

Thus, the claims are rejected.

Response to Arguments

Applicant's arguments and the Declaration by Dr. Kerr under 37 CFR 1.132 filed July 14, 2006 have been fully considered but they are not persuasive.

Applicant indicates that the Tu et al. publication, previously submitted, teaches the formation of complexes that enables SHIP to hydrolyze the 5'-phosphate on PIP3, thus preventing membrane recruitment and activation of pleckstrin homology (PH) domain containing kinases that serve as effectors of PI3K signaling. SIP-110 was also shown to have enzymatic activity by Jefferson et al. (Applicant's response, page 6, 2nd parag.; see also Dr. Kerr's declaration, point 2). In response, while Applicant provides biochemical studies indicating the relationship of s-SHIP/SIP-110 to other proteins, the specification and art do not provide guidance that loss of s-SHIP/SIP-110 results in mouse or human ES or hematopoietic cell proliferation without differentiation. Applicant indicates that the results described in the manuscript of Exhibit B (Desponts et al., 2006, Blood, 107: 4338-4345, previously cited) show that SHIP-deficiency in the HSC of mice

enhances HSC proliferation and survival (Applicant's response, page 7, 1st parag.). In response, this is not persuasive because the teachings of Desponts et al. do not support Applicant's assertion that s-SHIP has a role in the proliferation of HSC. According to Desponts et al., the SHIP-/- mice were generated by deletion of the promoter and first exon of SHIP via a Cre-LoxP strategy (Desponts, et al., page 4339, 1st col., 1st parag. under "Mice"). However, according to the art, s-SHIP mRNA is transcribed from a promoter within the intron between exons 5 and 6 of the SHIP1 gene and subsequently, SHIP1 knockout mice that have been generated by deleting the first exon express s-SHIP (Rauh et al., 2004, Biochemical Society Transactions, 32: 785-788, page 786, 1st col., 2nd parag.). As such, Desponts et al. do not support the assertion that s-SHIP has a role in hematopoietic stem cell proliferation (Applicant's response, page 7, 1st parag.). Subsequently, because it is not clear what relationship s-SHIP has with cell proliferation in hematopoietic cells, it is not clear what relationship s-SHIP has with cell proliferation in ES cells.

The results of the SHIP-/- mice also raise another issue. It is noted that the mice is a null for full length SHIP, but still express s-SHIP in hematopoietic cells. In the situation where an artisan would administer anti-s-SHIP shRNA to hematopoietic cells an artisan would effectively be reducing the mRNA levels of full length SHIP and s-SHIP. As indicated above with regard to the unpredictability in the art as it applies to determining what signals are involved in determining cell fate, an artisan cannot predict what phenotype a hematopoietic cell would have upon reduction in mRNA of full length

SHIP and s-SHIP. As such, an artisan is not enabled for the full breadth of the claimed invention.

Applicant indicates that Kavanaugh et al. 1996, Current Biology, 6: 438-445, supplied by Applicant, teaches that SIP-110 (the human homolog of mouse s-SHIP) binds with Grb2 and hydrolyzes PIP3, likely preventing PIP3 accumulation to significant levels (Kavanaugh et al., page 443, first column). Applicant indicates, like SHIP, SIP-110 opposes PI3K and thus, PI3K-effector pathways, which control cell proliferation and/or survival. In response, this is not found persuasive because while it may be presumed that reducing the levels of SIP-110 may lead to an increase in proliferation, via reducing the opposing activity that s-SHIP/SIP-110 has on PI3K, the art teaches that there are other signaling pathways that are associated with s-SHIP, such that an artisan cannot reasonably predict that the net result of s-SHIP reduction is reduction of PI3K suppression. For example, Rohrschneider et al., 2000, Genes and Development, 14: 505-520, teach that in the C-terminus of SHIP, there are SH3 and NPXY motifs which can bind SH2 and SH3 containing proteins. One protein found to bind to the C-terminus is PIAS, a protein inhibitor of STAT1 (Rohrschneider et al., page 512, 2nd col., under "PIAS1 interaction with SHIP"). As such, an artisan cannot reasonably predict that reduction of s-SHIP mRNA levels would reasonably result in cell proliferation.

Applicant indicates that RNAi affects the abundance of RNA and in turn the abundance of protein. Applicant also indicates that RNAi can be used to create hypomorphs as well as complete silencing (Applicant's response, page 8, 2nd parag.). In response, as indicated above, an artisan is not enabled to use RNAi (shRNA) in the

claimed invention to arrive at proliferating mouse and human ES and hematopoietic stem cells. While the steps of making shRNA/RNAi are understood at the time of filing, the art does not teach how to predict phenotypes in cells following shRNA/RNAi administration to a cell. In particular for hypomorphs, the art teaches that an artisan cannot reasonably predict that a hypomorph is a reduced form a phenotype; rather the art teaches that there are cases where a hypomorph can exhibit unpredictable phenotypes. As such, the specification does not provide guidance to arrive at proliferating ES or hematopoietic stem cells.

Applicant indicates that consideration is to be given to post-filing date evidence (e.g. Declarations and Exhibits) offered by the applicants to show that the claimed invention works provided that the evidence is consonant with the teachings of the specification as filed (Applicant's response, page 9, parag. under statement by Dr. Kerr). In response, while an Examiner can take into consideration Declarations and Exhibits, specific steps and embodiments used to arrive at the claimed invention which were not known at the time of filing cannot make a specification sufficient (the Examiner discussed this issue with respect to In re Glass, Final Action, April 12, 2006, page 5). As discussed above, the art teaches a variety of issues which require that an artisan would need to perfect, in order to arrive at the claimed invention. While Applicant asserts that an artisan of ordinary skill would reasonably expect that sufficient s-SHIP/SIP-110 knockdown could be achieved to induce proliferation, growth and/or survival of ESC and HSC, an assertion is not evidence (Applicant's response, page 9). Applicant indicates that the enablement requirement does not require that the applicants

reinvent the wheel (Applicant's response, page 9). In response, Applicant is claiming a novel method of arriving at proliferating ES and hematopoietic cells. According to the teachings in the art, the steps involved in inducing proliferation in cells are not well known; subsequently, an artisan cannot reasonably predict that one would arrive at the claimed invention.

It is noted that the rejection of claims 41, 42, 48, 49 is withdrawn as the claims are cancelled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32, 35 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 depends on claim 31, which is cancelled. For purposes of compact prosecution, claim 32 has been interpreted to be read on claim 29. Claim 35 depends on claim 32 and thus has been included in the rejection.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service

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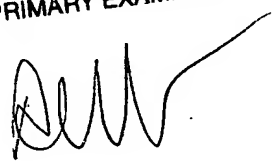
JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER



SCORE Search Results Details for Application 10605452 and Search Result us-10-605-452c-3.rag.

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SUMMARIES

Result No.	Score	% Query Match	Length	DB	ID	Description
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2	11198	43.6	5820	8	ADP31118	Adp31118 Human sec
3	10998.5	42.8	6729	8	ADP31600	Adp31600 Human sec
4	10885	42.4	4848	8	ADP31259	Adp31259 Human sec
5	10801.5	42.1	5514	8	ADP31186	Adp31186 Human sec
6	10801.5	42.1	5514	8	ADP31591	Adp31591 Human sec
7	10754.5	41.9	10944	8	ADP31311	Adp31311 Human sec
8	10754.5	41.9	11328	8	ADP31310	Adp31310 Human sec
9	10683.5	41.6	4683	8	ADP31260	Adp31260 Human sec
10	10639	41.4	7285	6	ABJ38280	Abj38280 pAMG21-RA
11	10562	41.1	5397	8	ADP31068	Adp31068 Human sec
12	10516.5	41.0	8976	8	ADP31425	Adp31425 Human sec
13	10516.5	41.0	9195	8	ADP31494	Adp31494 Human sec
14	10488	40.8	4360	8	ADP30525	Adp30525 Human sec
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17	9952.5	38.8	4752	8	ADP30585	Adp30585 Human sec
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19	9932	38.7	5304	8	ADP30706	Adp30706 Human sec
20	9883	38.5	3907	5	ABG70822	Abg70822 Mouse myo
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22	9398	36.6	3585	8	ADP31117	Adp31117 Human sec
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41	8816	34.3	4440	6	ABU82046	Abu82046 Novel hum
42	8816	34.3	4440	6	ABU07907	Abu07907 Novel hum
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ALIGNMENTS

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ID ADP31119 standard; protein; 8973 AA.
XX
AC ADP31119;
XX
DT 01-DEC-2005 (revised)
DT 12-AUG-2004 (first entry)
XX
DE Human secreted protein SEQ ID #3117.
XX
KW Cytostatic; Antiinflammatory; Immunosuppressive; Antibacterial; Virucide;
KW cancer; inflammatory; immune; human secreted protein.
XX
OS Homo sapiens.

XX
PN WO2004035732-A2.
XX
PD 29-APR-2004.
XX
PF 28-AUG-2003; 2003WO-US026780.
XX
PR 29-AUG-2002; 2002US-0406576P.
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PA (FIVE-) FIVE PRIME THERAPEUTICS INC.
XX
PI Williams LT, Chu K, Lee E, Hestir K, Beaurang PA, Behrens D;
PI Halenbeck RF, Huang MM, Kothakota S, Haishan L, Linnemann T;
PI Pierce K, Wang Y, Wong JGP, Wu G, Zhang H;
XX
DR WPI; 2004-348438/32.
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PT New nucleic acid molecule for diagnosing, preventing or treating diseases
PT such as proliferative (e.g. cancer), inflammatory, immune, metabolic,
PT genetic, bacterial and viral diseases.
XX
PS Claim 1; SEQ ID NO 3117; 428pp; English.
XX
CC The present invention relates to an isolated nucleic acid molecule
CC encoding a polypeptide which is believed to be cytostatic,
CC antiinflammatory, immunosuppressive, antibacterial and virucidal. The
CC composition and methods are useful for diagnosing, preventing and
CC treating diseases such as proliferative (e.g. cancer), inflammatory,
CC immune, metabolic, genetic, bacterial and viral diseases. The present
CC sequence represents a human secreted protein. The present sequence is
CC available on WIPOWEB and is not in the specification. Note: This sequence
CC is represented as a 3-letter coded protein in the corresponding sequence
CC listing but appears to be a polynucleotide sequence.
CC
CC Revised record issued on 01-DEC-2005 : Sequence description line
CC corrected
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Query Match 44.4%; Score 11404; DB 8; Length 8973;
Best Local Similarity 39.0%; Pred. No. 0;
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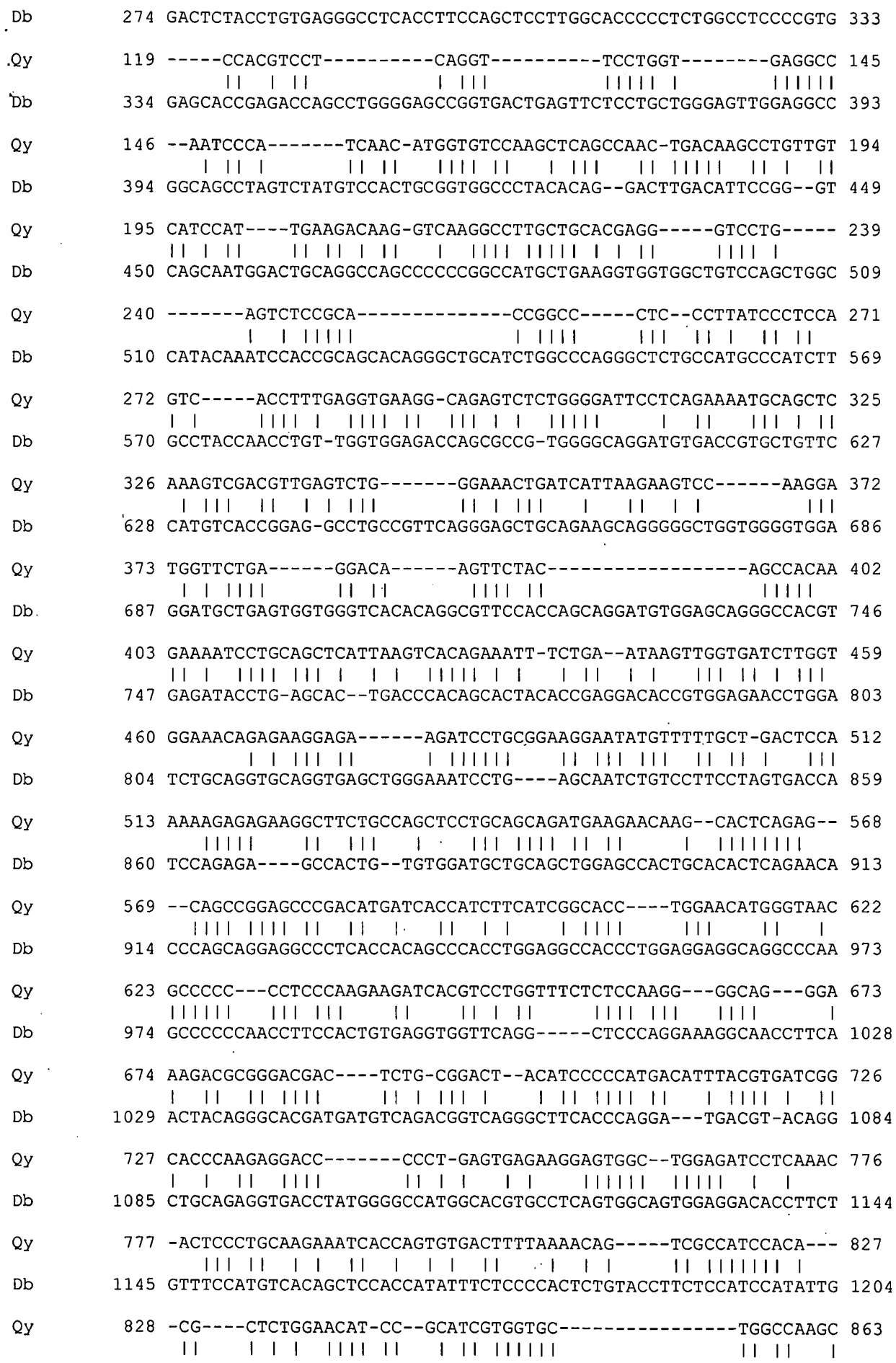

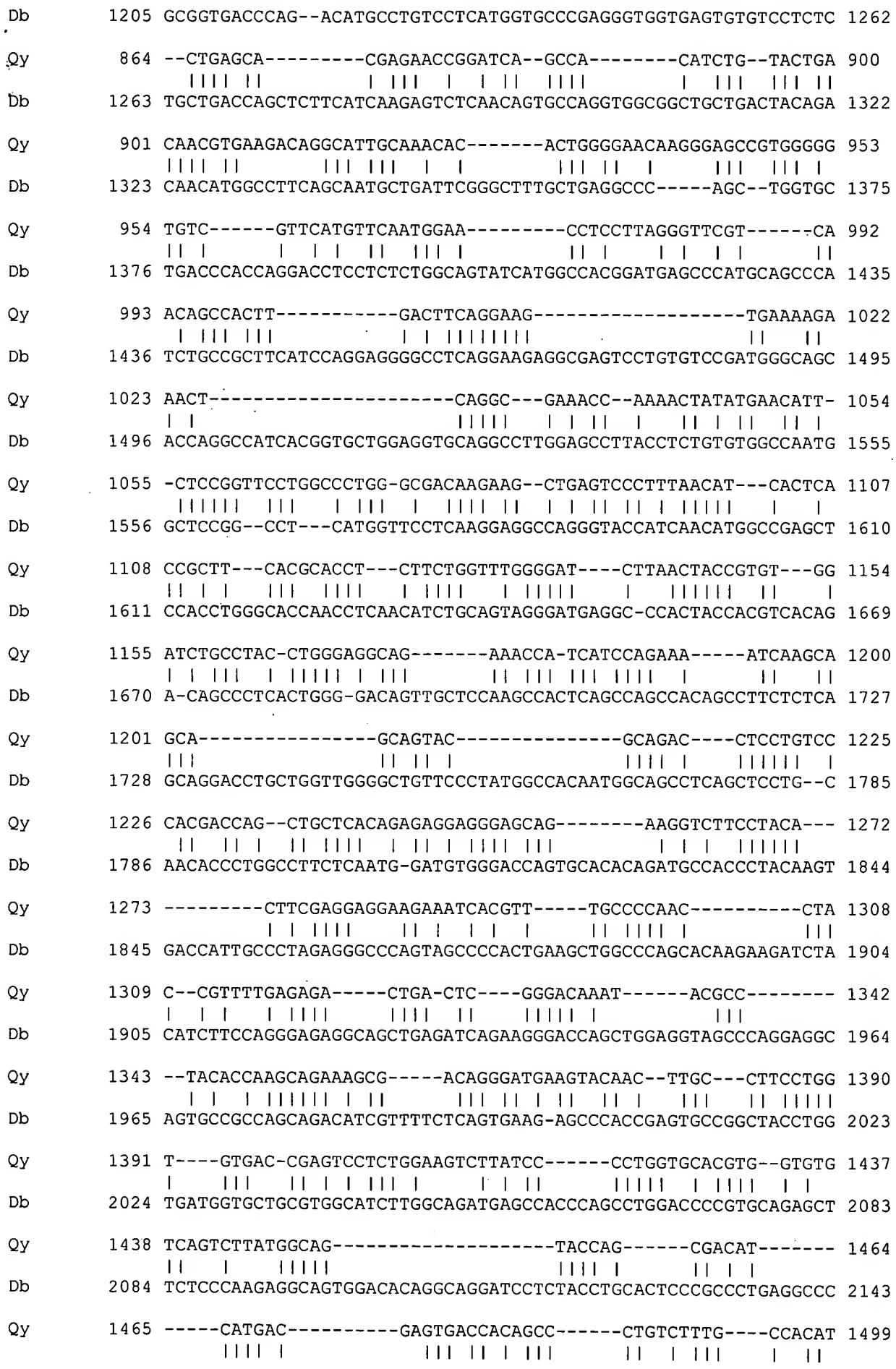

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Qy       1500 TTGAGGCAGGAG------TCACTTC----CCAGTTTGT-CTC--------CAAGA----- 1535
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Qy       1536 ACG-----GTCCCG--GG--------ACTG---TTGACAGCCAAGGACAGATTGAG--TT 1575
              |||     |||| |  ||         |||   | ||| ||||  | ||   || |   |
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Qy       1576 TCTCAGGTGCTATGC--CACATTGAAGACCAAGTCCCAGACCAAATTCTA-------CCT 1626
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Db       2383 GCAGAGGCTCT-GAGGAGCATGGATGGTTACTCTGGGCCCAAGGACCTGGTGTACACCAT 2441

Qy       1682 GAAGAA---------------GGAAGTGAGG-GGGAGCTGGTGG----TGA-AGTTTGGT 1720
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Db       2442 TAAGCAGCCCAGCAATGGGTGGGTAGTGCGGTGGGCGGTGCCGGGCACTGAGAGTCCGTC 2501

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Qy       1799 -----------------TC-CTCTGACAGCGA------------------CGAATCCTAT 1822
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SCORE Search Results Details for Application 10605452 and Search Result us-10-605-452c-2.rag.

This page gives you Search Results detail for the Application 10605452 and Search Result us-10-605-452c-2.rag.

start

Go Back to previous page

GenCore version 5.1.9

OM protein - protein search, using sw model

Run on: July 28, 2006, 17:25:50 ; Search time 330.813 Seconds
(without alignments)
5448.236 Million cell updates/sec

Title: US-10-605-452C-2
Perfect score: 24009
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Scoring table: BLOSUM62
Gapop 10.0 , Gapext 0.5

Searched: 2589679 seqs, 457216429 residues

Total number of hits satisfying chosen parameters: 2589679

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

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Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

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6	10100.5	42.1	11328	8	ADP31310	Adp31310 Human sec
7	10077.5	42.0	5397	8	ADP31068	Adp31068 Human sec
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9	10034	41.8	5514	8	ADP31186	Adp31186 Human sec
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11	10029.5	41.8	4683	8	ADP31260	Adp31260 Human sec
12	9987.5	41.6	9195	8	ADP31494	Adp31494 Human sec
13	9958	41.5	8976	8	ADP31425	Adp31425 Human sec
14	9931	41.4	4360	8	ADP30525	Adp30525 Human sec
15	9779	40.7	6465	8	ADP30705	Adp30705 Human sec
16	9667.5	40.3	7339	6	AAO16358	Aao16358 Human tra
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18	9588.5	39.9	4752	8	ADP30651	Adp30651 Human sec
19	9409.5	39.2	3907	5	ABG70822	Abg70822 Mouse myo
20	9409.5	39.2	3907	6	ABG74190	Abg74190 Mouse myo
21	9391.5	39.1	5304	8	ADP30706	Adp30706 Human sec
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41	8748.5	36.4	4440	6	ABU94227	Abu94227 Novel hum
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ALIGNMENTS

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ID ADP31119 standard; protein; 8973 AA.
XX
AC ADP31119;
XX
DT 01-DEC-2005 (revised)
DT 12-AUG-2004 (first entry)
XX
DE Human secreted protein SEQ ID #3117.
XX
KW Cytostatic; Antiinflammatory; Immunosuppressive; Antibacterial; Virucide;
KW cancer; inflammatory; immune; human secreted protein.
XX
OS Homo sapiens.

XX

PN WO2004035732-A2.

XX

PD 29-APR-2004.

XX

PF 28-AUG-2003; 2003WO-US026780.

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PA (FIVE-) FIVE PRIME THERAPEUTICS INC.
XX
PI Williams LT, Chu K, Lee E, Hestir K, Beaurang PA, Behrens D;
PI Halenbeck RF, Huang MM, Kothakota S, Haishan L, Linnemann T;
PI Pierce K, Wang Y, Wong JGP, Wu G, Zhang H;
XX
DR WPI; 2004-348438/32.
XX
PT New nucleic acid molecule for diagnosing, preventing or treating diseases
PT such as proliferative (e.g. cancer), inflammatory, immune, metabolic,
PT genetic, bacterial and viral diseases.
XX
PS Claim 1; SEQ ID NO 3117; 428pp; English.
XX
CC The present invention relates to an isolated nucleic acid molecule
CC encoding a polypeptide which is believed to be cytostatic,
CC antiinflammatory, immunosuppressive, antibacterial and virucidal. The
CC composition and methods are useful for diagnosing, preventing and
CC treating diseases such as proliferative (e.g. cancer), inflammatory,
CC immune, metabolic, genetic, bacterial and viral diseases. The present
CC sequence represents a human secreted protein. The present sequence is
CC available on WIPOWEB and is not in the specification. Note: This sequence
CC is represented as a 3-letter coded protein in the corresponding sequence
CC listing but appears to be a polynucleotide sequence.
CC
CC Revised record issued on 01-DEC-2005 : Sequence description line
CC corrected
XX
SQ Sequence 8973 AA;

Query Match 44.1%; Score 10582; DB 8; Length 8973;
Best Local Similarity 36.6%; Pred. No. 0;
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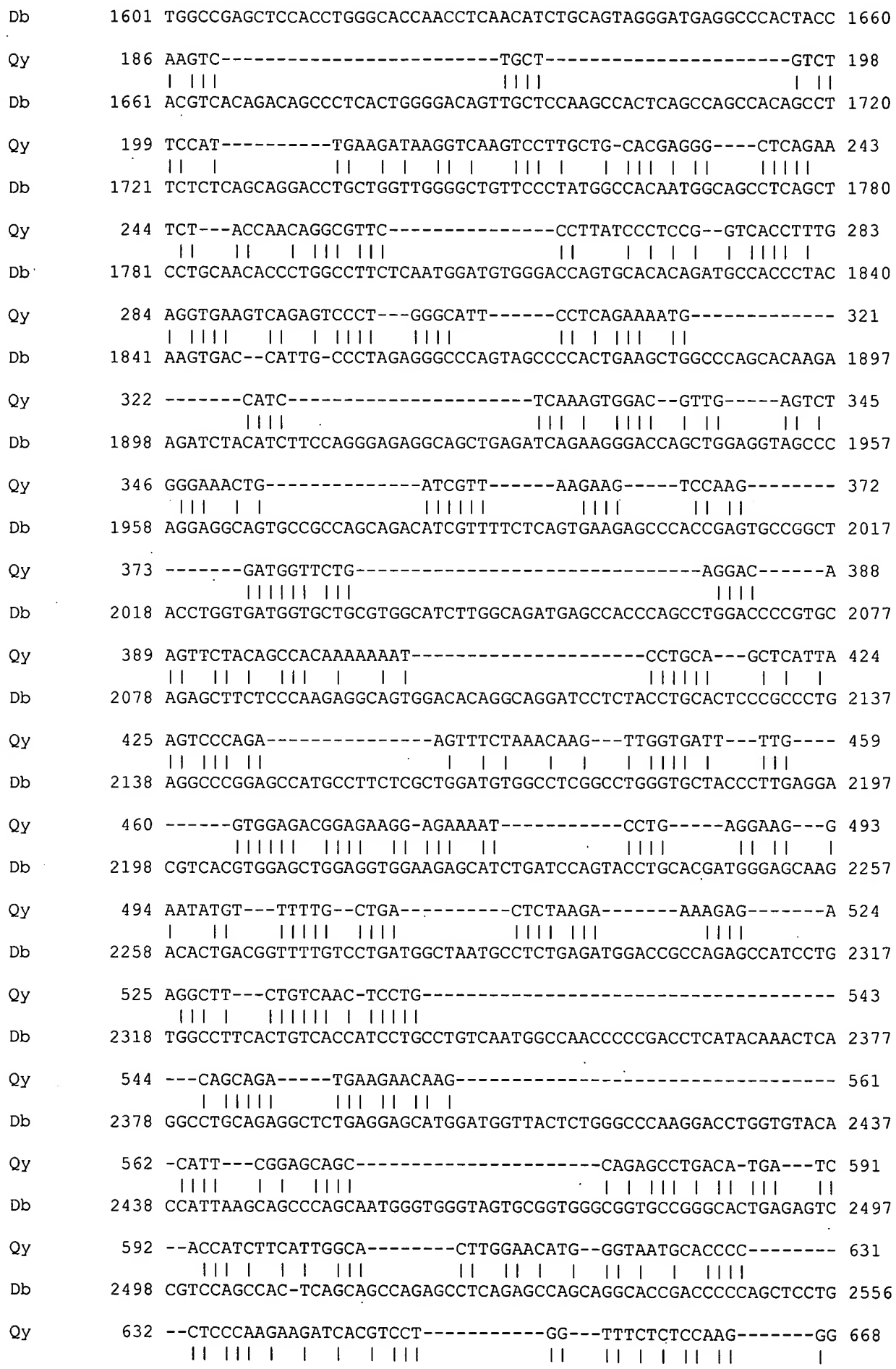

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Db       2674 GAGCCGCTGGCCAATATGTACTCATGTGGGAACCAGAACACACTGATGGAGGAGTTGGCA 2733

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Db       2794 AGCATCATCGGTGACATCAACAGGACCACTGTTACCATGCCCCCGCCCGTGGACGACACC 2853

Qy        835 TG-----------GAACAT---------------------------------TCGCATA 849
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Db       2854 TGGTTGCAGGTGCAGAGCATCCCTGACGCACACAGGCCAGAGGCTTCCCCTGATCCCTTT 2913

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Qy        980 ---CCTTGGGGTTCGTCAACAGCCACTTGACTT--------------------CTGGA-A 1015
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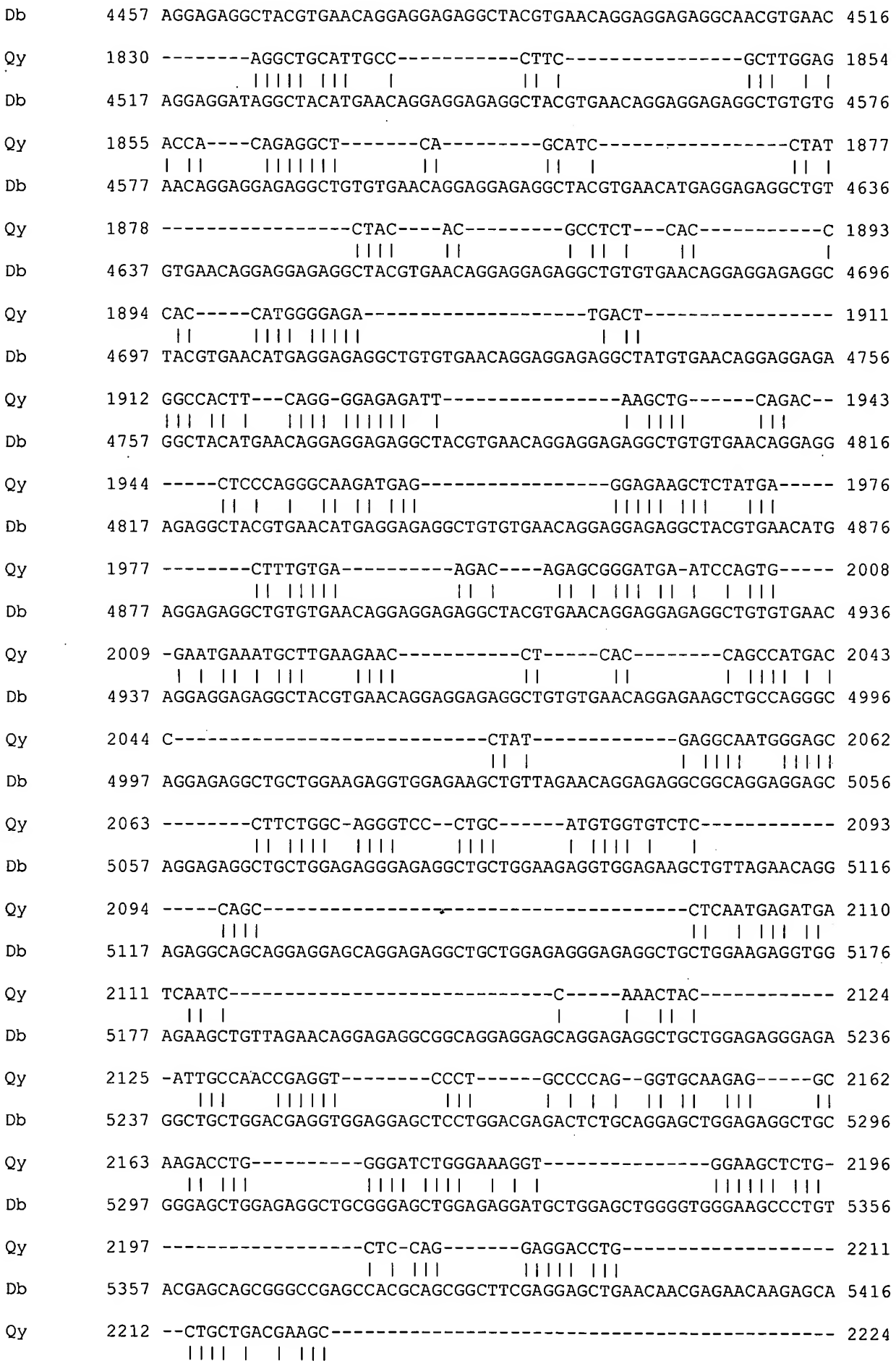

SCORE Search Results Details for Application 10605452 and Search Result us-10-605-452c-1.rag.

This page gives you Search Results detail for the Application 10605452 and Search Result us-10-605-452c-1.rag.

start

Go Back to previous page

GenCore version 5.1.9

OM protein - protein search, using sw model

Run on: July 28, 2006, 17:25:50 ; Search time 346.17 Seconds
(without alignments)
5448.236 Million cell updates/sec

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Scoring table: BLOSUM62
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Searched: 2589679 seqs, 457216429 residues

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Post-processing: Minimum Match 0%
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Listing first 45 summaries

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10: geneseqp2006s:*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

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ALIGNMENTS

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DT   01-DEC-2005  (revised)
DT   12-AUG-2004  (first entry)
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DE   Human secreted protein SEQ ID #3117.
XX
KW   Cytostatic; Antiinflammatory; Immunosuppressive; Antibacterial; Virucide;
KW   cancer; inflammatory; immune; human secreted protein.
XX
OS   Homo sapiens.
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XX

PN WO2004035732-A2.

XX

PD 29-APR-2004.

XX

PF 28-AUG-2003; 2003WO-US026780.

XX

PR 29-AUG-2002; 2002US-0406576P.
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XX
PA (FIVE-) FIVE PRIME THERAPEUTICS INC.
XX
PI Williams LT, Chu K, Lee E, Hestir K, Beaurang PA, Behrens D;
PI Halenbeck RF, Huang MM, Kothakota S, Haishan L, Linnemann T;
PI Pierce K, Wang Y, Wong JGP, Wu G, Zhang H;
XX
DR WPI; 2004-348438/32.
XX
PT New nucleic acid molecule for diagnosing, preventing or treating diseases
PT such as proliferative (e.g. cancer), inflammatory, immune, metabolic,
PT genetic, bacterial and viral diseases.
XX
PS Claim 1; SEQ ID NO 3117; 428pp; English.
XX
CC The present invention relates to an isolated nucleic acid molecule
CC encoding a polypeptide which is believed to be cytostatic,
CC antiinflammatory, immunosuppressive, antibacterial and virucidal. The
CC composition and methods are useful for diagnosing, preventing and
CC treating diseases such as proliferative (e.g. cancer), inflammatory,
CC immune, metabolic, genetic, bacterial and viral diseases. The present
CC sequence represents a human secreted protein. The present sequence is
CC available on WIPOWEB and is not in the specification. Note: This sequence
CC is represented as a 3-letter coded protein in the corresponding sequence
CC listing but appears to be a polynucleotide sequence.
CC
CC Revised record issued on 01-DEC-2005 : Sequence description line
CC corrected
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SQ Sequence 8973 AA;

Query Match 44.0%; Score 11079.5; DB 8; Length 8973;
Best Local Similarity 37.0%; Pred. No. 0;
Matches 2728; Conservative 0; Mismatches 1319; Indels 3335; Gaps 422;

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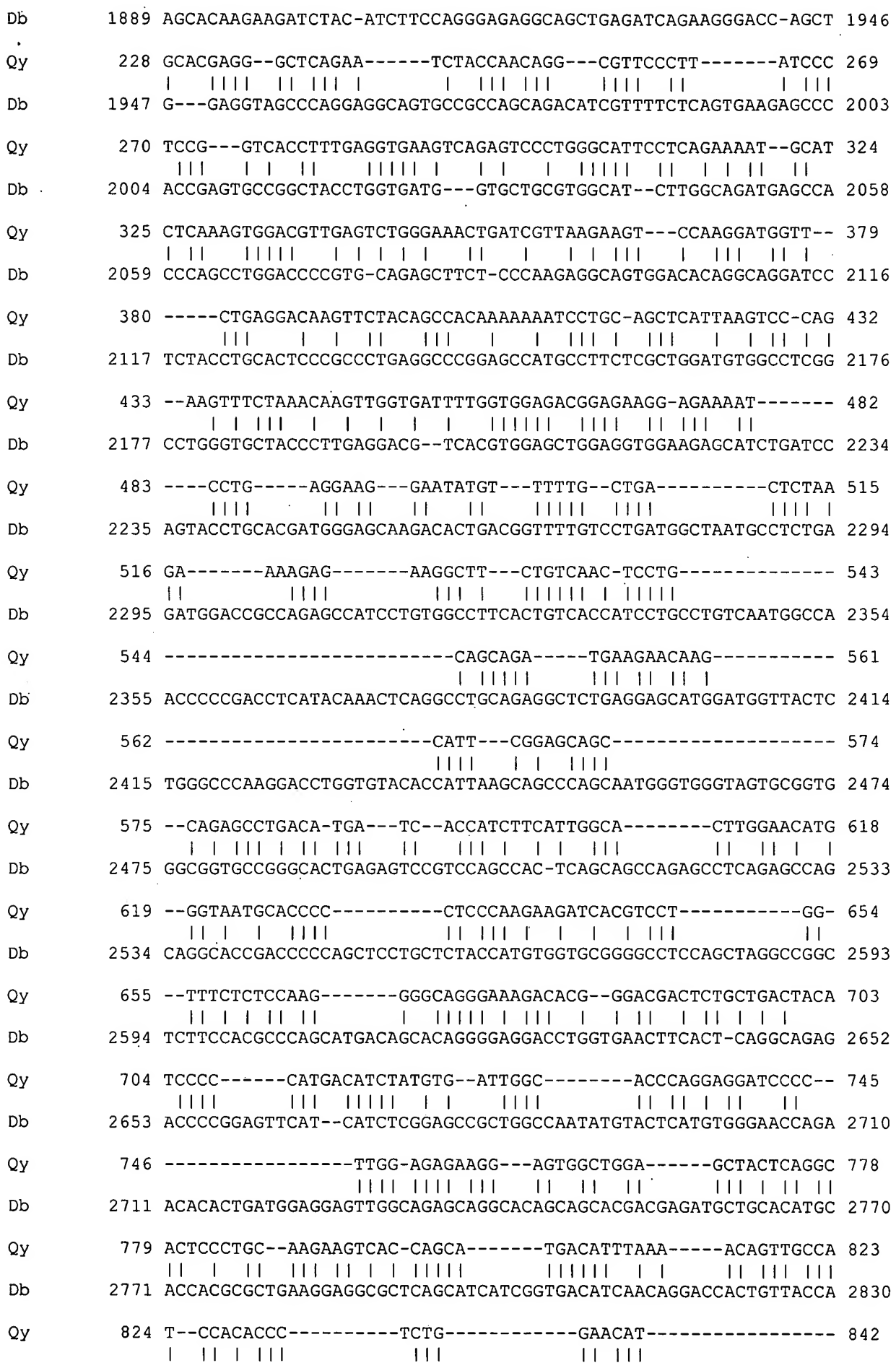

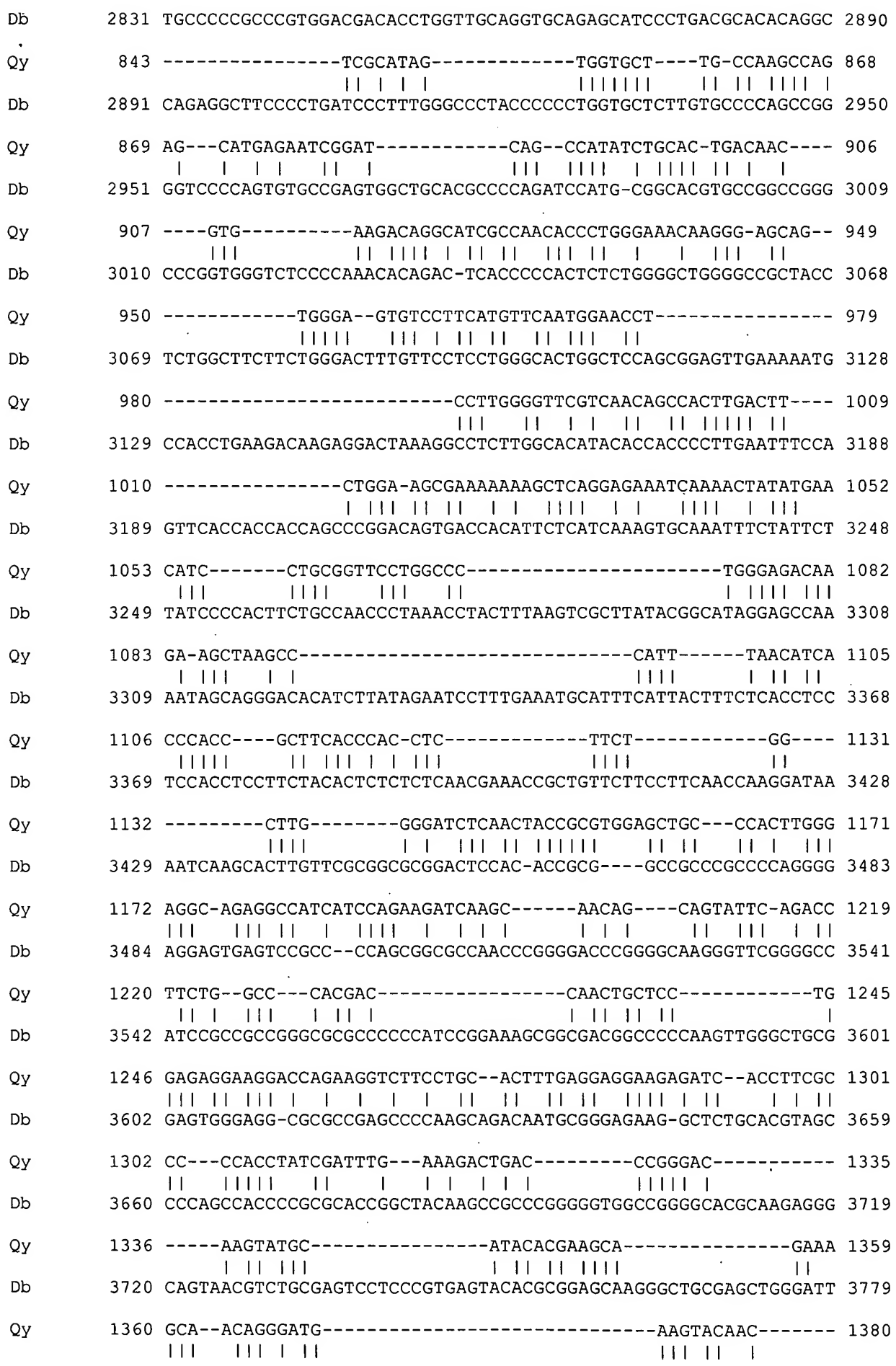

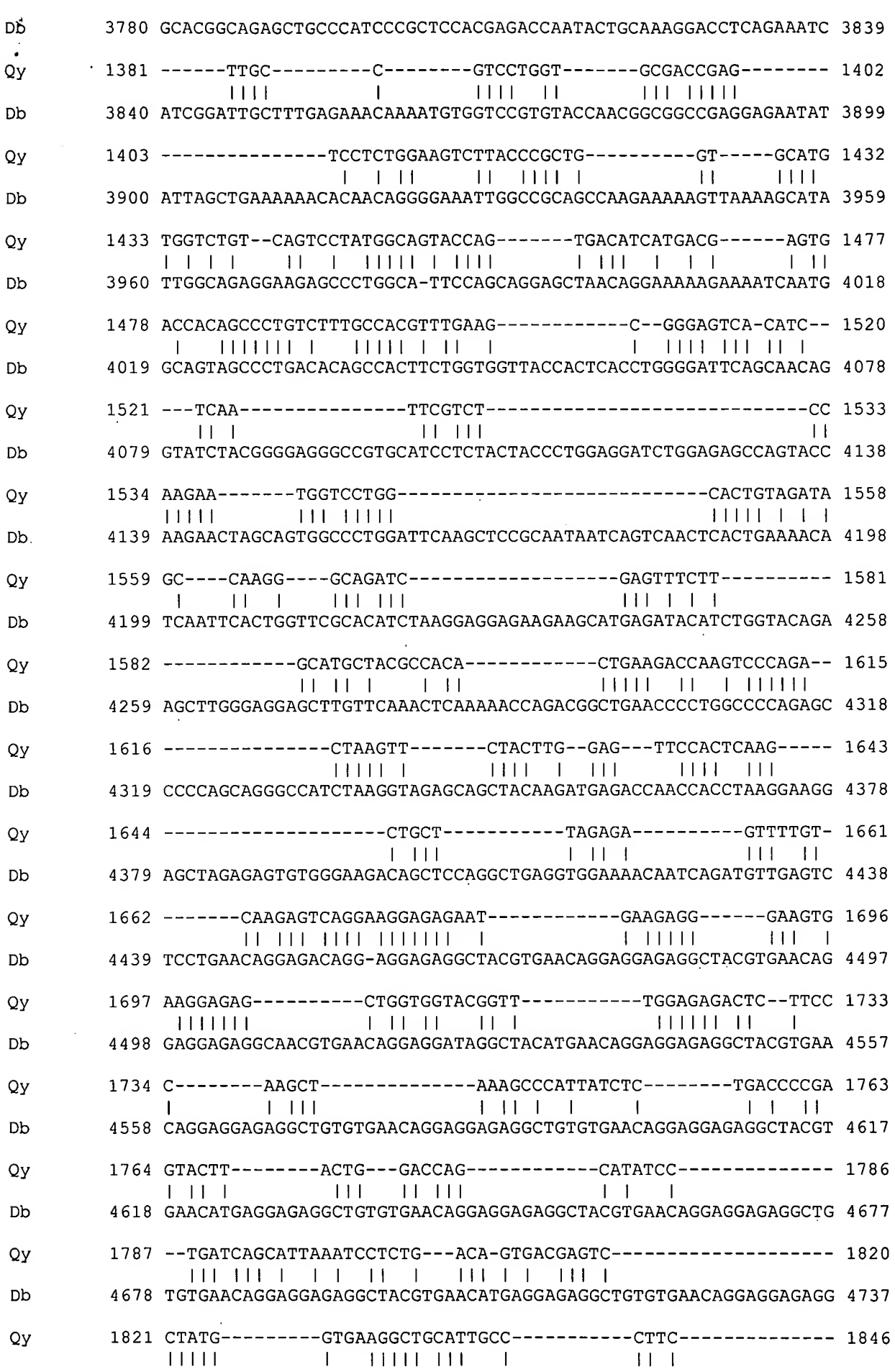

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Db       4738 CTATGTGAACAGGAGGAGAGGCTACATGAACAGGAGGAGAGGCTACGTGAACAGGAGGAG 4797

Qy       1847 --GCTTGGAGACCA----CAGAGGCTCAG----CAT--------CCTAT---------- 1877
                |||  | || ||     |||||||  |    |||          || |
Db       4798 AGGCTGTGTGAACAGGAGGAGAGGCTACGTGAACATGAGGAGAGGCTGTGTGAACAGGAG 4857

Qy       1878 ------CTACACG--CCT---------CT-----CAC----------CCAC-----CAT 1899
                   ||||  |  | |         ||      ||           | ||     ||
Db       4858 GAGAGGCTACGTGAACATGAGGAGAGGCTGTGTGAACAGGAGGAGAGGCTACGTGAACAG 4917

Qy       1900 GGGGAGATGACT----------------GGCCACTT---CAGG-GGAGAGATTAAG--- 1935
                | |||||  | ||               ||| || |   |||| ||||||  |  |
Db       4918 GAGGAGA-GGCTGTGTGAACAGGAGGAGAGGCTACGTGAACAGGAGGAGAGGCTGTGTGA 4976

Qy       1936 -CTGCAGAC-CTCCCAGGGCAAGA---------------------------------- 1957
                | | |||  || ||||||||  ||
Db       4977 ACAGGAGAAGCTGCCAGGGCAGGAGAGGCTGCTGGAAGAGGTGGAGAAGCTGTTAGAACA 5036

Qy       1958 ---------------------------------TGAGGGAGAAGCT-CT--ATGACTT 1979
                                               |||||||| ||| ||  | ||  |
Db       5037 GGAGAGGCGGCAGGAGGAGCAGGAGAGGCTGCTGGAGAGGGAGAGGCTGCTGGAAGAGGT 5096

Qy       1980 TGTGAAG--------ACAG-------AGCGGGATGA----------ATCCAGTGGAATGA 2014
                | ||||       ||||       ||| ||| ||          | | |  ||  ||
Db       5097 GGAGAAGCTGTTAGAACAGGAGAGGCAGCAGGAGGAGCAGGAGAGGCTGCTGGAGAGGGA 5156

Qy       2015 AATGCT-----------TGAAGAACCT---------------------------------- 2030
                | |||           || |||| ||
Db       5157 GAGGCTGCTGGAAGAGGTGGAGAAGCTGTTAGAACAGGAGAGGCGGCAGGAGGAGCAGGA 5216

Qy       2031 ----------------------------------------CACC-AGCCATGACCCT 2046
                                                        | ||  | |  ||| ||
Db       5217 GAGGCTGCTGGAGAGGGAGAGGCTGCTGGACGAGGTGGAGGAGCTCCTGGACGAGACTCT 5276

Qy       2047 ----------ATGAGGCAATGGGAGC--------CTTCTG-------------------- 2068
                         |||||   ||||||        || | |
Db       5277 GCAGGAGCTGGAGAGGCTGCGGGAGCTGGAGAGGCTGCGGGAGCTGGAGAGGATGCTGGA 5336

Qy       2069 GCAGGG-------TCCCTGCATGTG---------GTGTCTC----CAGCCTCAATGAGAT 2108
                || |||        |||||  | | |         | | | |    | || || | ||| |
Db       5337 GCTGGGGTGGGAAGCCCTGTACGAGCAGCGGGCCGAGCCACGCAGCGGCTTCGAGGAGCT 5396

Qy       2109 GATCA-----ATC-----CAAACTACA-TTG---------GTATGGGGCCTTTTG--GAC 2146
                || ||     | |     || ||| || |||         |||  ||  ||   |  | |
Db       5397 GAACAACGAGAACAAGAGCACACTGCAGTTGGAGCAGCAAGTAAAGGAGCTGAAGAAGTC 5456

Qy       2147 AG--CCCCTGCATGGGAAATCAACC-CTGTCCC------------------CAGATC-- 2182
                |     ||| | | ||   |||| | | |||                  |  |||
Db       5457 GGGTGAGCTGAAAGAGACTGTAACCTCCGACCCATCCAAGAAGATGTGGGAGCCAATCGT 5516

Qy       2183 --------AGCAACTCACA----------GCT------TGGAGTTA----TGACCAGCTA 2214
                       || |||| |||           ||      |||||  |    ||    ||
Db       5517 GTTTAAGGAGAAACTAACAATGAAAACGGACTCGTTGATGGAGGAAAAGTTGGAATGCAG 5576

Qy       2215 CC----------------CAAAGACTCCTCCCTGGGGC-----------CTGGGAGGGGG 2247
                ||                |||   |||   || ||| |           |||| | || |
Db       5577 CCTCTGGTGCTGTTTGAGCAATCCCTCTATCCCGGGTCGCTGCTGTGTTCTGGAAAGGCG 5636

Qy       2248 GAGGGTCCTC------CAAC------CC-------CTCCCTCCC--------------- 2272
                |  || | |      || |      ||       || | || |
Db       5637 CATTGTACCCTGGATGCAGCAGGAATCCTATTCATCTTCTTCACCGATATGGTCTGTGGA 5696

Qy       2273 --------AACCACCTCTGTCGCCA-------------AAGAAGTT-------------- 2297
                       | |||  |||| |  ||             |||||
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